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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)	
BSI-540US	

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on November 26, 2008

Signature

Typed or printed name Cassandra Hann

Application Number	Filed
10/643,261	**August 20, 2003**
First Named Inventor	
Ilya Yampolsky	
Art Unit	**Examiner**
3734	**Kevin Thao Truong**

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.7.1 Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 41,964

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature

Joseph E. Maenner
Typed or printed name

610-407-0700
Telephone number

November 26, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

Claim status

Claims 1-12 are pending. Claims 13-17 have been canceled.

Remarks

Claims 1-12 stand rejected under 35 U.S.C. 103 as unpatentable over U.S. Patent No. 7,131,991 to Zarins et al. ("Zarins") in view of U.S. Patent No. 5,383,892 to Cardon et al. ("Cardon"). Applicants respectfully traverse this rejection.

Of the rejected claims, claim 1 is independent. Claim 1 recites, *inter alia*, a bifurcated stent being expandable from an unexpanded state to an expanded state. The stent comprises a trunk region having a self-expandable section constructed from a first material and a balloon expandable section constructed from a second material. The balloon expandable section extends from a first end of the self-expandable section. In the expanded state the balloon expandable section is less compressible than the self-expandable section. The stent also includes at least one self-expandable branch fixedly connected to and extending from a second end of the self-expandable section of the trunk region. In the expanded state the balloon expandable section is less compressible than the at least one self-expandable branch. *The self-expandable branch does not include a balloon-expandable section.*

The Office Action alleges that Cardon teaches that the end portion of a hybrid stent device should be balloon expandable in order to obtain the advantage of insuring that the device is anchored in the blood vessel. Office Action, page 2, para 2. Applicants respectfully submit that the Examiner failed to consider the full teaching of Cardon and therefore failed to show a proper reason to modify Zarins with Cardon. A *complete* reading of Cardon indicates that Cardon teaches a juxtaposition of axially rigid and axially flexible parts such that:

"there are *always*:

one axially rigid part at *each end* of the stent;

two axially rigid parts on either side of an axially flexible part."

Cardon, Col. 1, lines 49-51 (emphasis added).

Cardon also provides exemplary embodiments of his invention, where "the structures of the stents follow the sequences indicated hereinbelow:

1) rigid end part-flexible part-rigid end part

R-F-R

2) rigid end part-flexible part-intermediate part-flexible part-rigid end part

R-F-R'-F-R"

Id, Col. 1, line 65 - Col. 2, line 6.

Again, Cardon recites that "the stents according to the invention *always* have rigid ends." *Id*, Col. 2, lines 54-55 (emphasis added). Such an arrangement enables stents according to Cardon's invention to fasten securely to the walls of the parts of the human body in which they are implanted and minimizes the risk of disturbances in the flow of fluids circulating in the parts of the human body. *Id*, Col. 1, lines 53-57. Therefore, instead of disclosing a self-expandable branch that is more compressible than a balloon expandable section, Cardon teaches relatively rigid ends at *both* ends.

More specifically, an exemplary embodiment of the stent of the present invention includes a trunk having a mechanically or balloon-expandable proximal section that is adapted to firmly engage that part of the body lumen surrounding the proximal section. Specification, page 5, lines 21-22. The mechanical or balloon-expandable proximal section has greater rigidity, which prevents the stent from working its way from its originally deployed position. *Id*, page 6, lines 18-24. The stent further includes the trunk having a distal section and branches that share a common compressibility that is adapted to permit the distal section and the branches to conform to the shape of the body lumens surrounding them at their deployment site and to be easily advanced through the tortuous confines of the body lumens. *Id*, page 5, lines 15-19.

In attempting to combine the teaching of Cardon with the teaching of Zarins, the Office Action ignores the requirement in Cardon that *both* ends of the stent be rigid and therefore fails to show a proper reason for making the proposed modification of Zarins with Cardon. As stated in M.P.E.P. §2141.02 VI, however, "[a] prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 202 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)."

In *Bausch & Lomb v. Barnes-Hind/Hydrocurve*, 230 U.S.P.Q. 416 (CAFC 1986), the defendant selected a single line from a prior art reference to support its assertion that the process disclosed in the reference was exactly the same as the process claimed in the patent-in-suit. The court, however, held that the statement relied upon by the defendant was taken out of context and stated that a full appreciation of the statement required consideration of the immediately following sentences in the same paragraph and the paragraph after that. *Id*. Similarly, in the

present case, while the Examiner alleges that Cardon teaches that the end portion of a hybrid stent device should be balloon expandable, such statement is being taken out of context. The Examiner must also take into consideration the *total* teaching of Cardon, which clearly teaches that there is *always* one axially rigid part at *each end* of the stent.

Because, in accordance with M.P.E.P. §2141.02 VI, Cardon must be considered in its entirety, a person of ordinary skill in the art, having Cardon in front of him and seeking to modify Zarins with the teaching of Cardon, would understand that such modification requires *both* ends of Zarins to be axially rigid. The result of this modification would result in a bifurcated stent having a branch with a relatively rigid end.

Further, "it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *In re Wesslau*, 353 F.2d 238 at 241, 147 USPQ 391 at 393 (CCPA 1965). As discussed above, Cardon clearly states the stents according to his invention *always* have relatively rigid ends. This statement clearly suggests to one of ordinary skill in the art that if one is to look to Cardon to modify Zarins by incorporating a rigid end at one end of the Zarins stent, one cannot ignore the requirement that *both* of the ends be rigid, and must therefore also incorporate a rigid end at the other end of the Zarins stent. By *requiring* one relatively rigid part *at each end* of the stent, the proposed combination of Zarins and Cardon teaches away from claim 1, which precludes a balloon expandable (relatively rigid) section anywhere in the branch, let alone at the end of the branch.

In the Advisory Action dated November 14, 2008, the Examiner cites *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985) to support the proposition that "the fact that Applicants have recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." Advisory Action, page 2, lines 10-12.

It is respectfully submitted that advantages conferred by the preferred embodiments of the claimed invention do not naturally flow from the hypothetical combination of references cited by the Examiner. In fact, the prior art teaches away from such advantages. In an exemplary embodiment of the claimed invention, for example, the balloon expandable region is the upstream portion of the stent, which

is used to engage the body lumen, while the self-expandable region, which is the downstream portion of the stent, allows the stent to flex with movement of the body lumen. An advantage conferred by such embodiment is that it provides a stent having a balloon expandable section of the trunk region that has greater rigidity, which helps prevent the stent from working its way from its originally deployed position, while providing for flexibility and movement of the self-expandable region downstream of the balloon expandable region. If one were to combine Zarins with Cardon as suggested by the Examiner, however, the downstream end of the stent would also be rigid, significantly reducing the downstream flexibility.

Because Cardon, when taken as a whole, teaches away from a balloon expandable section in the trunk region and a self-expandable branch extending from a self-expandable section of the trunk region, *wherein the self-expandable branch does not include a balloon-expandable section*, the proposed combination of Zarins with Cardon is improper. Applicants respectfully submit that the rejection of claim 1 is improper and request reconsideration and allowance of claim 1.

Claims 2-12 all ultimately depend from claim 1. Applicants respectfully submit that claims 2-12 are allowable over the proposed combination of Zarins and Cardon for at least the same reasons set forth above with respect to amended claim 1. Applicants respectfully request reconsideration and allowance of claims 2-12.

Conclusion

In light of the above remarks, Applicants respectfully submit that the present application is in condition for allowance. Applicants respectfully request reconsideration and allowance of the claims.